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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,994	09/22/2006	Satoshi Tanabe	442P105	3238
42754	7590	01/22/2009		
Nields, Lemack & Frame, LLC 176 E. Main Street Suite #5 Westborough, MA 01581			EXAMINER KLINKEL, KORTNEY L.	
			ART UNIT	PAPER NUMBER
			1611	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/593,994

Applicant(s)

TANABE ET AL.

Examiner

Kortney L. Kinkel

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s) Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s) Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

Receipt is acknowledged of remarks filed 10/6/2008.

Claims 2-3 were canceled.

Claims 1, and 5-7 were amended.

Claims 1, and 4-9 are pending in the instant Office Action.

All rejections/objections not addressed herein have been withdrawn.

Response to Arguments

Terminal Disclaimer

The terminal disclaimer filed on 6/6/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending application serial number 10/593920 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Therefore the rejection of claims 1-7 under Double Patenting is withdrawn.

Rejection of claims 1-7 under 35 USC § 102(a)

Applicant's arguments, see page 2-3, filed 10/6/2008, with respect to the rejection of claims 1-7 under 35 USC § 102(a) as being anticipated by Tanabe et al. JP2003146810 have been fully considered and are persuasive in light of the front pages of document WO 2005/102050 (the publication of the PCT application through which the

instant application was filed) and JP2003146810. These cover pages, originally published in Japanese, clearly show that the inventorship is the same in both documents. Accordingly, JP2003146810 does not constitute prior art and the rejection is withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-5, 7 and 9 are rejected under 35 U.S.C. 102 (b) as being anticipated by Hotta et al. JP6092935 (JP6092935, all references to which are in regard to the machine translation).

Hotta teaches a composition comprising N-substituted indole derivatives identical to those of the instant invention and their use as an insecticide in order to protect man or animal from parasitic hindrance ([0001]). Hotta discloses the instant N-substituted indoles of formula (I) and their use in an insecticidal composition (Detailed Description of the Invention, paragraphs 0003-0006 and 0029 for specific types of fleas). Hotta claim 4 recites the same three compounds as instant claim 4. Hotta teaches that the indole derivatives can be mixed with a liquid carrier, an emulsifier, a dispersant, or a disintegrator among other excipients (paragraphs [0017]-[0019]).

Applicant is reminded that the phrases "flea control" with respect to agent, "percutaneous" with respect to preparation, "for controlling fleas", "wherein the fleas to be controlled are fleas parasitic on companion animals" are all intended uses. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitations of the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). See also MPEP 2112-2112.02.

Since the only required element of the instant claims is an N-substituted indole derivative represented by general formula (I) and that this general formula (I) is taught by Hotta and Hotta further teaches use of these compounds in an insecticidal composition useful for the protection of man or animal from parasitic hindrance, and that this composition can be in liquid form, the compositions of Hotta could be used as a "flea control", and "percutaneously".

Response to Arguments

Applicant's arguments filed 10/6/2008 with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. However, the examiner will address the pertinent arguments regarding Hotta.

Applicant argues that the data of test examples 1 and 2 demonstrate that compounds 14, 17, and 25 (the compounds of instant claim 4) have low toxicity to mouse and cat while maintaining high insecticidal activity against cat flea as

demonstrated in Examples 4 and 5. Applicant argues that Hotta neither teaches nor suggests that the N-substituted indole derivatives of formula (I) have these properties. Applicant concludes that therefore, the inventions of the claims are fundamentally different from the teachings of Hotta et al.

As addressed above, the phrases "flea control" with respect to agent, "percutaneous" with respect to preparation, "for controlling fleas", "wherein the fleas to be controlled are fleas parasitic on companion animals" are all intended uses. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitations of the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). See also MPEP 2112-2112.02.

Since the only required element of the instant claims is an N-substituted indole derivative represented by general formula (I) and that this general formula (I) is taught by Hotta and Hotta further teaches use of these compounds in an insecticidal composition useful for the protection of man or animal from parasitic hindrance, the compositions of Hotta could be used as a "flea control", and/or "percutaneously". Additionally because Hotta teaches the instant compounds, the compounds would inherently exhibit low toxicity to mouse and cat while maintaining high insecticidal activity against fleas, as suggested in the instant examples for specific concentrations and dosing amounts, since that property is inherent to the instant compounds.

Applicant has not claimed any element or ingredient to distinguish the instant compositions from those taught by Hotta.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hotta et al. (JP6092935, all references to which are in regard to the machine translation).

Hotta teaches a composition comprising N-substituted indole derivatives identical to those of the instant invention and their use as an insecticide in order to protect man or animal from parasitic hindrance ([0001]).

With respect to claims 6 and 8 which recite a shampoo or rinse for controlling fleas, Hotta teaches that the N-substituted indole derivatives can be diluted with water and used as needed. Hotta also teaches that the indole derivatives can be mixed with a liquid carrier, an emulsifier, a dispersant, or a disintegrator among other excipients (paragraphs [0017]-[0019]).

Hotta does not explicitly teach the use of the N-substituted indoles as a shampoo or rinse, however, as alluded to above, Hotta describes that the indole derivatives can be mixed with an emulsifier and/or a liquid carrier. Emulsifiers such as surface-active agents are the major functional component of shampoos. The term "rinse" implies a liquid and Hotta teaches that the compositions comprising the N-substituted indoles can be in liquid form. As such, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to arrive at the instant shampoo or rinse compositions comprising N-substituted indoles with a reasonable expectation for success.

Applicant is reminded that the phrases "flea control" with respect to agent, "percutaneous" with respect to preparation, "for controlling fleas", "a shampoo or rinse for controlling fleas", "wherein the fleas to be controlled are fleas parasitic on companion animals" are all intended uses. A recitation of the intended use of the claimed invention

must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitations of the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). See also MPEP 2112-2112.02.

Since the only required element of the instant claims is an N-substituted indole derivative represented by general formula (I) and that this general formula (I) is taught by Hotta and Hotta further teaches use of these compounds in an insecticidal composition useful for the protection of man or animal from parasitic hindrance, and that this composition can be in liquid form, the compositions of Hotta could be used as a "flea control", "percutaneously" and in the form of "a shampoo or rinse for controlling fleas".

Response to Arguments

Applicant's arguments filed 10/6/2008 with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. However, the examiner will address the pertinent arguments regarding Hotta.

Applicant's arguments and the Examiner's response regarding Hotta are set forth above. In addition to that discussed above, Applicant argues that Hotta describes at paragraphs [0016] and [0017] that the instant indoles can be mixed with agricultural chemical adjuvants such as a liquid carrier, an emulsifier, etc. and this fact distinguishes the teachings of Hotta from the instant invention. This argument is not found persuasive. The phrase agricultural-chemicals adjuvants is an exceedingly broad and

rather generic descriptor. This phrase does not exclude the possibility of shampoos and rinses. Furthermore there are several known adjuvants, including emulsifiers that are useful both in the agricultural and shampoo arts. Water is an excellent example. The first sentence of [0017] states that water can be added to the indole compositions. The simple addition of water to the indoles would constitute a rinse. Applicant has not structurally defined a "rinse" to distinguish it from the prior art.

Applicant has provided no unexpected results. The argument that test Examples 1-2 and 3-4 demonstrate that compound 14, 17 and 25 have low toxicity to mouse and cat while maintaining high insecticidal activity against fleas merely demonstrates the action of an insecticide. Hotta teaches that the N-substituted indole derivatives are insecticides, therefore one would expect them to be capable of killing fleas, which are insects. "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967).

Furthermore, it is noted that the examples a specific concentration of indole derivative is used on specific species of flea (i.e. cat flea) with specific excipients and/or solvents. However, the instant claims do not recite any concentrations nor any excipients. The only ingredient listed in the instant claims is the N-substituted indole derivative.

Conclusion

Claims 1, and 4-9 are rejected. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Sharmila Gollamudi Landau/
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